

Attorney Docket No.: **KUZ-0024**  
Inventors: **ITO et al.**  
Serial No.: **10/531,433**  
Filing Date: **April 15, 2005**  
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**REMARKS**

Claims 1-3, 5-7, 10-14, 16 and 17 are pending in the instant application. Claims 1-3, 5-7, 10-14, 16 and 17 have been rejected. Claims 2, 6, 7 and 16 have been amended. Claims 1, 5, 10, 11, and 12 have been canceled. New claims 21, 22, 23 and 24 have been added. Support for these amendments is provided in the original claims as well as teachings in the specification at page 1, lines 9-12, page 3, lines 23-26, page 5, lines 5-17, pages 6-9 and the Examples beginning at page 13. Thus no new matter is added by these amendments. Reconsideration is respectfully requested in light of these amendments and the following remarks.

**Rejection of Claims under 35 U.S.C. 103(a)**

The rejection of claims 1-3, 5-7, 10-14, 16 and 17 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent 5,814,032 issued to Hori et al. ("Hori") has been maintained.

Applicants respectfully traverse this rejection.

Claims of the instant patent application have been amended to be drawn to a transdermal patch for external use having a backing layer and a pressure-sensitive adhesive layer formed on one surface of the backing layer, consisting

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essentially of polyisobutylene, a mineral oil and fentanyl as an active ingredient in the pressure-sensitive adhesive layer, contents of polyisobutylene and fentanyl in the pressure-sensitive adhesive layer respectively ranging from 75.2 to 94.2% by mass and 1 to 6% by mass while the content of the mineral oil being from 0.25 to 0.05 parts by mass based on polyisobutylene and a transdermal patch for external use having a backing layer and a pressure-sensitive adhesive layer formed on one surface of the backing layer, consisting essentially of polyisobutylene, a mineral oil, a percutaneous absorption enhancer and fentanyl as an active ingredient in the pressure-sensitive adhesive layer, contents of polyisobutylene and fentanyl in the pressure-sensitive adhesive layer respectively ranging from 75.2 to 94.2% by mass and 1 to 6% by mass while the content of the mineral oil being from 0.25 to 0.05 parts by mass based on polyisobutylene.

Support for this amendment can be found in the specification at, for example, page 1, lines 9-12, page 3, lines 23-26, and page 5, lines 5-17, pages 6-9. Further support is provided in the Examples beginning at page 13 of the specification, each only containing PIB, the mineral oil liquid paraffin and fentanyl or PIB, the mineral oil liquid paraffin, a percutaneous absorption enhancer and fentanyl.

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In contrast, the Hori patent teaches as an essential element to the adhesive layer of their transdermal patch, 5 to 50% by weight of a hygroscopic material. See Abstract, col. 1, lines 52-64, col. 4, line 24 through col. 5, line 9 and the Examples of the Hori patent.

Accordingly, the Hori Patent provides no reasonable expectation of success with respect to the instant claimed transdermal patch which does not require as an element a hygroscopic material, but which still demonstrates excellent adhesive property, cohesive property, adhesion property and remaining of adhesive mass to the skin. See Table 1 and page 20 of the instant specification.

MPEP 2144.04 and the case law are clear; the omission of an element and retention of its function is an indicia of unobviousness. *In re Edge*, 359 F.2d 896, 149 USPQ 556 (CCPA 1966). Clearly, the instant claimed transdermal patches, which do not require as an essential element a hygroscopic material taught by the Hori Patent to be required for skin adhesive properties and low skin irritating properties, but which still demonstrate excellent adhesive property, cohesive property, adhesion property and remaining of adhesive mass to the skin are unobvious over the Hori patent.

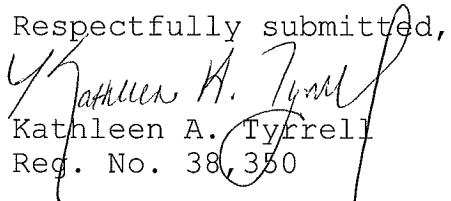
Withdrawal of this rejection under 35 U.S.C. 103(a) is

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respectfully requested.

**Conclusion**

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of all pending claims is earnestly solicited.

Respectfully submitted,  
  
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